**Introduction**

- In the U.S., there are over 34 million MRI and 80 million CT scans performed annually.
- Prior to imaging, contrast media is injected into the patient to enhance the contrast of the images.
- Bayer sells 40 million DP-1000 spikes per year to transfer the contrast media from stock bottles to the injector system.

![Figure 1: Image before (left) and after (right) contrast media injection](image1.png)

![Figure 2: Bayer’s Stellant Injector System](image2.png)

**Problem**

The DP-1000 Bayer Spike leaks from the contrast bottle:
- Approximately 90% of filling sequences from the vent filter
- Approximately 25% of filling sequences (>20 mL purge volume)

Leaks are the #1 customer complaint because they waste media, hinder workflow, and damage injector systems.

![Figure 3: Spike transfer contrast media (green) to the injector system (white)](image3.png)

![Figure 4: Leaks from the air vent (above) and spike tip (below)](image4.png)

**Prototyping**

- Our team assisted Bayer in development of a **proprietary spike design to reduce leaks** from the air vent and the contrast bottle during removal.
- Prototype parts were **3-D printed** for feasibility testing, and then **injection molded** for the final design.

![Figure 5: DP-1000 Spike](image5.png)

![Figure 6: New Prototype](image6.png)

**Testing**

- The efficacy of the new spike design and its ability to transfer contrast were investigated.
- The new prototype spike was compared with the original DP-1000 spike on the Stellant injector system.
- Filling sequences using flow rates (1-10 mL/s), purge volumes (10-30 mL), and glycerine water were utilized.
- **Qualitative observations and quantitative measurements** determined if spikes were leaking fluid from the vent port or upon removal of the bottle from the spike.
- Quantitative measurements not shown for IP protection.

![Figure 7: Testing set-up](image7.png)

**Results**

- Compared to the DP-1000 spike, our prototype:
  - Prevents 100% of leaks from air vent and contrast bottle.
  - Costs no more to manufacture.
  - Requires no additional procedures and training.
  - Maintains form factor.
  - Received positive feedback from experienced CT technologists.

**Conclusion & Future Directions**

Our prototype features a disposable spike that prevents all leaks and spillage during use and disposal.

Future directions:
- Finalize design details to ensure manufacturing feasibility.
- Establish quality control system with supplier.
- Build a business case and explore possible price increase options.

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